

S-Methoprene
PC Codes: 000802
Product Chemistry; Tox and Non-Target Waivers

DP Number: 406469
EPA File Symbol Number: 89363-R



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

DATE: 06/24/2013

SUBJECT: Science Review in Support of the Registration of Sequent S-Methoprene Technical, Containing 96.66% S- Methoprene as its Active Ingredient. Unregistered Source of the Active Ingredient.

Decision Numbers: 467979
DP Numbers: 406469
Submission No. 925290
EPA File Symbol Numbers: 89363-R
Chemical Class: Biochemical
PC Code: 105402
CAS Number: 65733-16-6
Tolerance Exemption.: 40 CFR 180.1033
MRID Numbers: 488922-01 & -02

FROM: Russell S. Jones, Ph.D., Senior Biologist /s/ 06/24/2013
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

A handwritten signature in black ink, appearing to read "Russell S. Jones".

TO: Cheryl Greene, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

On behalf of SeQuent Scientific Limited, M. R. Schneider submitted a request for the registration of SeQuent S- Methoprene Technical (EPA File Symbol No. 89363-R), containing 96.66% S- Methoprene as its active ingredient. The TGAI/MP is manufactured with an unregistered source of the active ingredient. The applicant is claiming substantial similarity to two currently registered products [EPA Reg. Nos. 74032-1 (95.5% a.i.) & 82122-1 (95.5% a.i.)] . The registrant additionally claims that their product has approximately 1.5% greater purity than the

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two currently registered products. The applicant is using the "Cite-All" method in support of the data requirements (except for product chemistry) and has offered to provide data compensation to the existing registrants.

RECOMMENDATIONS AND CONCLUSIONS

1. The submitted product chemistry data are UNACCEPTABLE, but upgradeable. To Upgrade the product chemistry submission to Acceptable, the registrant must:
 - a. identify the "single major impurity" listed on the CSF [REDACTED]; all components present in the formulation present at ≥ 0.1 % w/w must be listed on the CSF;
 - b. resolve the differences between the product name listed on the on the CSF and the product name listed on the product label;
 - c. provide the quality control procedure(s) used to ensure the active ingredient is within the proposed product specifications;
 - f. provide details concerning the formation of the "single major impurity" and the "sum of other methoprene-related impurities";
 - h. address the following Physical and Chemical Characteristics data requirements:
 - i. oxidation/reduction:chemical incompatibility;
 - ii. dissociation constant in water;
 - iii. a one-year storage stability and corrosion characteristics study (under normal conditions of storage);
 - iv. viscosity, and
 - v. partition coefficient testing
 - i. Waivers from the aforementioned data requirements under Conclusion 1h above cannot be granted on the basis that no information was found by the registrant in NPIRS. These data are required.
 - j. Storage stability studies conducted under "accelerated" (i.e. elevated temperature) storage conditions are not sufficient to fulfill the data requirements for storage stability. The Accelerated (14-day) Storage Stability study contained in MRID 48892201 is considered SUPPLEMENTAL by the Agency.

Manufacturing process information may be entitled to confidential treatment

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NOTE 1: It is noted that there is a discrepancy between MRID 48892201 and the CSF in regard to the amount of cis-methoprene present in the product; the Agency will default to the nominal concentration listed on the CSF.

NOTE 2: For the aforementioned data requirements discussed in Conclusion 1h, data for an accelerated storage stability study are not sufficient to address the data requirement of a one-year storage stability study. Data for one-year storage stability and corrosion characteristics study conducted under normal conditions of storage for this product are required. The data requirements for viscosity, partition coefficient, oxidation/reduction:chemical incompatibility, dissociation constant in water must be addressed. If those data requirements are not applicable for this product, the registrant must state that they are not applicable (NA) and provide a reason for their respective lack of applicability. The method used to determine pH must be provided.

2. All Tier I Toxicity and Tier I Non-Target Organisms data are bridged from the currently registered TGAI/MPs [EPA Reg. Nos. 74032-1 (95.5% a.i.) & 82122-1 (95.5% a.i.)] to support the data requirements for the registration of SeQuent S- Methoprene Technical (EPA File Symbol No. 89363-R). No additional data are required.

STUDY SUMMARIES

Product Chemistry (MRID 48892201):

SeQuent S-Methoprene Technical (EPA File Symbol 89363-R) is a technical grade active ingredient/manufacturing use product intended for formulation into end use products intended for agricultural crops; ornamental plants and forest trees; processed or manufactured products; food-handling premises; food or feed containers or dispensers; pets and domestic animals and their man-made premises; households; aquatic sites; noncrop, wide area and general indoor/outdoor treatments; or commercial, domestic and industrial uses. The applicant states that SeQuent S-Methoprene is substantially similar to the registered products (S)-Methoprene Technical R-ST SM Insect Growth Regulator (EPA Reg. No. 74032-1) and (S)-Methoprene Technical (EPA Reg. No. 82122-1). The product contains 96.66% w/w S-methoprene [isopropyl (2E, 4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate] as its active ingredient. The CSF and product label are in agreement concerning the content of active ingredient in the product. Impurities associated with the active ingredient are [REDACTED] w/w cis-methoprene, [REDACTED] w/w "single major impurity," [REDACTED] w/w "sum of other methoprene-related impurities," and [REDACTED] w/w water. There are no intentionally-added inert ingredients in the product. SeQuent S-Methoprene Technical is produced using a four-step integrated process. An acceptable description of the manufacturing process was provided, with the exception that the quality control procedures to ensure the product is within specifications were not discussed. The discussion of the formation of impurities did not address the formation of the "single major impurity" or the "sum of other methoprene-related impurities." There is a discrepancy between MRID 48892201 and the CSF

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concerning the amount of cis-methoprene allowed in the product; the Agency defaults to the values stated on the CSF. Acceptable results of a five-batch analysis were submitted. The certified limits for the active ingredient are within the OCSPP-recommended range. Upper and lower certified limits are provided for the impurities, although only upper limits are required. The enforcement analytical method is gas chromatography with flame ionization detection, and an acceptable description was provided. Waivers were requested for one-year storage stability and corrosion characteristics, viscosity, and partition coefficient testing.

Oxidation/reduction: chemical incompatibility and dissociation constant in water were not addressed, and the method to determine pH was not provided.

For additional details see attached DER for MRIDs 48892201, 48892202

cc: R. S. Jones, C. Greene, BPPD Chron File, IHAD/ARS
Russell S. Jones, Ph.D., Sr. Scientist, FT, PY-S: 06/24/2013